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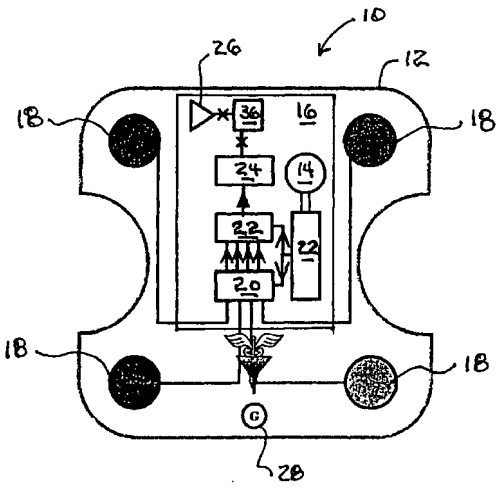
(54) Title: WIRELESS MEDICAL MONITORING APPARATUS AND SYSTEM



(57) Abstract: An apparatus for monitoring an electrical signal from a patient's body includes a disposable electrode patch (10) having a thin flexible housing (12) with an adhesive exterior, a power source (14), a printed circuit board (16), a plurality of electrodes (18), a convertor (20) for converting a detected electrical signal from the patient's body to a digital signal, a processor (22) for processing the digital signal, and a transmitter (24) connected for transmitting the processed digital signal as a wireless signal. A monitoring unit (40) communicating with the electrode patch includes a power source, a transceiver, a global positioning receiver, a processor, at least one communication port for external communications, and a display. A system of the invention includes a plurality of patients having medical monitors wirelessly communicating biometric information to a central processor for archiving and accessing.

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WIRELESS MEDICAL MONITORING APPARATUS AND SYSTEM

Related Application

This application claims priority from co-pending U.S. provisional application Serial No. 60/288,587, which was filed on May 3, 2001.

Field Of The Invention

The present invention relates to the field of medical monitoring of patients and, more particularly, to a disposable electrode patch and apparatus for wireless monitoring of medical patients.

Background Of The Invention

Monitoring of the electrical impulses generated by various organs is well known in medicine. For example, electro-cardiograms, electro-encephalograms, and other similar patient monitoring methods continue to be important elements in the medical armamentarium for combating disease.

Standard methods for such medical monitoring include the attachment of electrodes to the patient's body adjacent the organ to be monitored. These electrodes are generally connected by wires to an apparatus for recording any detected electrical signals and for displaying those signals in visually perceptible form, such as in a strip chart or in on a display screen. It is easy to appreciate the limitations imposed by the requirement that the electrodes be connected to the apparatus by wires. Patient mobility is severely limited, and the tests must generally be performed in a medical office or similar setting.

To avoid some of these inconveniences, monitoring apparatuses have been developed wherein the patient wears the electrodes connected by wire to a portable recording device which the patient carries usually on a harness, a belt, or some other support. The recording device must be

returned to the medical office for downloading and/or reading of the recorded data.

The aforementioned systems are unsuitable for monitoring multiple patients in real time. These prior systems are also not easily adaptable to manual activation by a patient in response to a medical event which should be recorded. Additionally, the old systems are necessarily dependent on cumbersome equipment not easily used directly by the patient.

Summary Of The Invention

With the foregoing in mind, the present invention advantageously provides a disposable electrode patch for monitoring of at least one electrical signal from a patient's body. The disposable patch comprises a flexible housing, a power source, electrically connected components including one or more electrodes, a signal converter, a processor, and a transmitter. The relatively thin and flexible sealed housing has an adhesive surface effective for releasably adhering the patch to the patient. The power source is positioned in the housing for providing power. A printed circuit board is positioned in the housing connected to the power source for thereby distributing power. At least one electrode is adjacent a surface of the housing and connected through the circuit board so as to detect the electrical signal when the patch is properly adhered to the patient's body. A converter is positioned in the housing connected through the circuit board to the at least one electrode for converting a detected electrical signal from the patient's body to a digital signal. The processor has a clock and is positioned in the housing connected through the circuit board to the converter for processing the digital signal responsive to time. A transmitter having a relatively flexible antenna is positioned in the housing connected to the processor through the circuit board for transmitting the processed digital signal as a wireless signal.

One preferred embodiment of the invention includes a monitoring unit comprising a power source, a transceiver in wireless communication with the disposable electrode patch, a global positioning receiver, a processor programmed at least to control the apparatus and to process signals received, at least one communication port for external communications, and a display connected to the processor to visually display information from signals processed thereby. The patient wears this monitoring unit, so that the patient's location may be tracked through the global positioning information provided by the monitoring unit.

The invention also includes a patient kit for use by a patient requiring medical monitoring. The patient kit comprises a carrying case disposed with interior cushioning material having a plurality of cavities therein for containing kit components. The various kit components are partly as described above, for example, a packet containing a plurality of disposable electrode patches, a monitoring unit, a charger for the rechargeable power source, and an instructional video recording containing instructions for the patient on proper use of kit components.

Further, the system of the invention may additionally be expanded to includea plurality of patients each individual patient of the plurality wearing a disposable electrode patch and a monitoring unit as described. A base station processor for monitoring the plurality of patients comprises a transceiver in wireless communication with each individual monitoring unit worn by the plurality of patients so as to receive therefrom signals processed thereby, and a display for displaying information contained in the received signals, including patient location information received from the global positioning system receiver.

Brief Description Of The Drawings

Some of the features, advantages, and benefits of the present invention having been stated, others will become apparent as the

description proceeds when taken in conjunction with the accompanying drawings in which:

FIG. 1 is a top plan schematic of a typical disposable electrode patch according to an embodiment of the present invention;

FIG. 2 shows an alternate embodiment of the disposable patch of FIG. 1, wherein the patch includes an adjustably extendable housing member;

FIG. 3 shows an alternate embodiment of the disposable patch of FIG. 1, wherein the patch has an extendable housing member pivotably connected to the housing;

FIG. 4 shows front, side, top and bottom elevation views of the monitoring unit used in conjunction with the patch of FIG. 1;

FIG. 5 depicts an alternate embodiment of the disposable electrode patch of the present invention, wherein the patch releasably connects to an existing electrode; and

FIG. 6 illustrates the carrying case for the patient kit embodiment of the invention.

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Detailed Description of the Preferred Embodiment

The present invention will now be described more fully hereinafter with reference to the accompanying drawings, in which preferred embodiments of the invention are shown. This invention may, however, be embodied in many different forms and should not be construed as limited to the illustrated embodiments set forth herein. Rather, these illustrated embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. Accordingly, FIGS. 1 through 6 illustrate the various aspects of the present invention.

A preferred embodiment of the invention includes a disposable electrode patch 10 for monitoring of at least one electrical signal from a patient's body. The disposable electrode patch 10 comprises several

elements: a relatively thin and flexible sealed housing 12 having an adhesive surface effective for releasably adhering the patch to the patient; a power source 14 positioned in the housing for providing power; a printed circuit board 16 positioned in the housing connected to the power source for thereby distributing power; at least one electrode 18 adjacent a surface of the housing and connected through the circuit board 16 so as to detect the electrical signal when the patch 10 is properly adhered to the patient's body; a converter 20 positioned in the housing connected through the circuit board 16 to the at least one electrode 18 for converting a detected electrical signal from the patient's body to a digital signal; a processor 22 having a clock and positioned in the housing connected through the circuit board 16 to the converter 20 for processing the digital signal responsive to time; and a transmitter 24 having a relatively flexible antenna 26 and positioned in the housing connected to the processor 22 through the circuit board 16 for transmitting the processed digital signal as a wireless signal.

Preferably, as shown in FIG. 1, the electrode patch 10 may further comprise a plurality of electrodes 18 having a sufficient number of individual electrodes for effectively detecting a cardiac electrical signal. The disposable electrode patch 10 may also include other preferable features, such as a ground electrode 28 for grounding the electrode patch to the patient's body. The patch 10 may include a plurality of electrodes wherein at least one individual electrode 18 of the plurality of electrodes is positioned on a housing member 30 extending outwardly from the housing so as to allow predetermined placement on the patient's body of the individual electrode spaced apart relative to the housing, as seen in FIGS. 2 and 3. In these embodiments, the housing member 30 is adjustably extendable from the housing (FIG. 2), or pivotably connected to the housing (FIG. 3). The electrode patch 10 preferably also includes a hardwire connector 32 for transmitting the processed digital signal by wire as a backup to wireless, as seen in FIGS. 2 and 3.

In additional aspects of the invention, the housing 12 is advantageously constructed from a plurality of laminated layers comprising woven material and plastic. As known to those skilled in the art, the electrode patch 10 includes electrodes having an electrically conductive gel. The circuit board 16 optionally comprises an activation switch 34 allowing a patient to manually activate the electrode patch 10

In another preferred embodiment, the transmitter 24 further comprises a transceiver for transmitting and receiving wireless signals, and further comprises an antenna filter for filtering radio interference. Also, the electrode patch 10 may include a light source 38, preferably a light-emitting diode, connected to the circuit board 16 to provide a visual indication of electrode patch activation. As a power source 14, the electrode patch 10 comprises a relatively flat, compact disposable battery.

Another embodiment of the invention includes an apparatus for wireless monitoring of at least one electrical signal from a patient's body. The apparatus includes the above-described disposable electrode patch 10, and a monitoring unit 40 comprising a power source 14, a transceiver in wireless communication with at least the electrode patch, a global positioning receiver, a processor 22 programmed at least to control the apparatus and to process signals received, at least one communication port 44 for external communications, and a display 46 connected to the processor 22 to visually display information from signals processed thereby. The monitoring unit 40 may further comprise an activation switch 48 for manually activating the apparatus. Generally, the monitoring unit 40 is sized so as to be portable by a patient wearing the electrode patch 10. In addition, the monitoring unit 40 may be disposed with a plurality of light sources 38, preferably light-emitting diodes, connected to function as visual indicators of apparatus status. To increase its utility, the monitoring unit 40 comprises a plurality of communication

ports 44, wherein at least one communication port comprises an RS-232 port, and one communication port is responsive to infrared light.

Among other features of the invention, it should be recognized that the monitoring unit power source 14 is best a rechargeable power source such as a lithium ion battery, or similar. The invention, therefore, also includes a battery charger for the monitoring unit 40, which operates in a known fashion. Additionally, the monitoring unit 40 includes a speaker 50 connected to provide an audible signal responsive to apparatus status, and at least one scroll switch 52 connected to allow a patient to scroll through information appearing on the display 46. Most advantageously, the monitoring unit 40 is remotely programmable from a base station processor communicating therewith through at least one individual communication port of the plurality of communication ports.

An alternate embodiment of the disposable electrode patch 10 is shown in FIG. 5. In this configuration the disposable electrode patch 10 comprises a relatively thin and flexible sealed housing 12 externally disposed with an adhesive effective for releasably adhering the patch to the patient, having an electrode docking port 54 positioned on an undersurface of the housing for therein engaging an electrode 18, and having a plurality of manually actuated stops adjacent the electrode docking port 54 for releasably securing an electrode therein engaged. Additional features of this alternate embodiment of the electrode patch 10 are as previously described. An electrode 18 releasably engaged in the electrode docking port 54 is part of the invention, so as to detect and communicate through the circuit board 16 the at least one electrical signal when the patch 10 is properly adhered to the patient's body. Other aspects of this embodiment include a converter 20 positioned in the housing 12 connected through the circuit board 16 to the electrode 18 for converting the detected electrical signal from the patient's body to a digital signal; a processor 22 having a clock and positioned in the housing connected through the circuit board 16 to the converter 20 for processing

the digital signal responsive to time; a transmitter 24 having a relatively flexible antenna 26 and positioned in the housing connected to the processor 22 through the circuit board 16 for transmitting the processed digital signal as a wireless signal; and a light source 38 connected to provide a visual signal indicative of functional status of the electrode patch 10.

It should be understood that this alternate embodiment of the electrode patch 10 forms part of the invention in combination with a monitoring unit 40 comprising a power source 14, a transceiver in wireless communication with at least the electrode patch, a global positioning receiver, a processor 22 programmed to control the apparatus and to process signals received, at least one communication port 44 for external communications, and a display 46 connected to the processor 22 for visually displaying information from signals processed thereby.

A further aspect of the present invention includes a patient kit 58 for use by a patient requiring medical monitoring. The kit 58 includes a carrying case 60 disposed with interior cushioning material having a plurality of cavities therein for containing kit components, which are: a packet containing a plurality of the disposable electrode patches, a monitoring unit 40, a charger for the rechargeable power source, and an instructional video recording containing instructions for the patient on proper use of kit components.

To expand the utility of the invention, a system is provided for monitoring a plurality of patients. In the system, each of a plurality of patients wears the disposable electrode patch 10 and a monitoring unit 40. A base station processor comprising a transceiver is in wireless communication with each individual monitoring unit 40 worn by the plurality of patients so as to receive therefrom the signals processed. A display 46 connected to the base station processor displays information contained in the received signals, including patient location information received from the global positioning system 42 receiver.

Those skilled in the art will appreciate several aspects of the invention, for example, that the various electronic components should be chosen for minimum power consumption, and that the transmitters and/or transceivers may operate in the common industrial/scientific/medical range of the wireless spectrum, such as from 900-960 MHz, or others. Also, that the wireless signals may be in standard formats such as code division multiple access (CDMA), time division multiple access (TDMA), global system for mobile communications (GSM), and AMPS/ANALOG. Typical gels for use in the electrodes include the well known HydraGel and SolidGel, both of which are trademarks for proprietary compositions of electrically conductive gels. A useful power source for use in the disposable electrode patch 10 is a Panasonic Br3032 battery, or any other similar battery with about 2500 hours of capacity. Preferred batteries are replaceable, although these would not necessarily be employed in the disposable electrode patch 10. The relatively flexible circuit board 16 may be manufactured of phenolic, acetate, and/or Mylar. It should also be apparent to the skilled that this invention is equally applicable in veterinary medicine as it is in human medicine. Additionally, the advantages of the patient kit 58 herein described should be recognized by the skilled as providing great, heretofore unavailable convenience for both patients and physicians.

A method aspect of the present invention includes a process for transmitting the medical monitoring data, also referred to herein as biometric data or biometric information, by short range radio frequency from the electrode patch 10 to the monitoring unit 40. The monitoring unit 40, in turn, transmits the data by wireless communication, preferably vi a cellular telephone system, to a local server computer. The local server computer then transmits the data to a central server computer, and for data safety preferably to two geographically separated central server computers which are mirror images of each other. One of these central server computers will generally act as the primary server, and the other

will remain as a mirror image backup. Medical data archived in the primary central server will be accessible through security controlled access via the Internet. Internet access may be accomplished through a portable computer or a desktop computer or other digital device such as a personal digital assistant (PDA), however, any such computer or device used for accessing the system must be capable of reading a user's fingerprint (preferably a thumb print) so that a registered user of the system may be identified and cleared for access by identification of his/her fingerprint.

The data is preferably accessed via the Internet by means of a separate Virtual Private Network (VPN), which will have access to a "download specific" database. "Download specific" means that only the biometric data of patients whose physician elects to access data via the VPN will be downloaded to this Internet accessible database.

In use, the biometric data and a unique identifier is transmitted short range from the electrode patch 10 to the monitoring unit 40 transceiver. The identifier is then encrypted and along with the biometric data they are transmitted first via cellular network then via a private intranet that uses frame relay, satellite and dedicated ISDN to transmit the data to two geographically separated collection points. Servers at the collection points will allow communication with the transceiver only if the signal includes a prearranged code that must match both the short range transmitter's own unique identifier and the transceiver's unique identifier. The communication will be accepted, and biometric data will be allowed into the network only after this "handshake" occurs.

Once biometric data is received at the collection points, each collection point will immediately duplicate the data and send it preferably over three separate communication lines: wirelessly via satellite, by a dedicated frame relay circuit, and by a dedicated ISDN circuit to two national data centers. These data centers are separated geographically, and run in tandem. Each collection point and each data center preferably

contains redundant systems as well as redundant power supplies and redundant emergency generators.

Any measurable or imaged data of the human body that is transmitted into this network is then archived or stored for as long as required by applicable regulations. These data are then made available via the described intranet almost immediately, preferably within minutes. It should be understood that these data are not medical records; but biometric data or images that support the doctor's diagnosis.

Each hardware component that communicates with the system must have both the computer processor 22's unique identifier and the network interface card's unique identifier registered with the network. Additionally, authorized individuals must also be registered with the network via registry of their fingerprint or thumb print prior to authorized access to the databases. The network will only allow access if the required fingerprint or thumb print is matched with both the computer's processor 22 and the network interface card's unique identifier as a set. Specific network configuration parameters will be implemented for both national and international use of the described system.

Accordingly, in the drawings and specification, there have been disclosed typical preferred embodiments of the invention, and although specific terms are employed, the terms are used in a descriptive sense only and not for purposes of limitation. The invention has been described in considerable detail with specific reference to these illustrated embodiments. It will be apparent, however, that various modifications and changes can be made in the spirit and scope of the invention as described in the foregoing specification and as defined in the appended claims.

THAT WHICH IS CLAIMED:

1. A disposable electrode patch for monitoring of at least one electrical signal from a patient's body, said patch comprising:

a relatively thin and flexible sealed housing having an adhesive surface effective for releasably adhering said patch to the patient;

a power source positioned in said housing for providing power;

a printed circuit board positioned in said housing connected to said power source for thereby distributing power;

at least one electrode adjacent a surface of said housing and connected through said circuit board so as to detect the electrical signal when the patch is properly adhered to the patient's body;

a converter positioned in said housing connected through said circuit board to said at least one electrode for converting a detected electrical signal from the patient's body to a digital signal;

a processor having a clock and positioned in said housing connected through said circuit board to said converter for processing the digital signal responsive to time; and

a transmitter having a relatively flexible antenna and positioned in said housing connected to said processor through said circuit board for transmitting the processed digital signal as a wireless signal.

2. The electrode patch of Claim 1, wherein said at least one electrode further comprises a plurality of electrodes having a sufficient number of individual electrodes for effectively detecting a cardiac electrical signal.

3. The electrode patch of Claim 1, further including a ground electrode for grounding the electrode patch to the patient's body.

4. The electrode patch of Claim 1, further comprising a plurality of electrodes wherein at least one individual electrode of said plurality of electrodes is positioned on a housing member extending outwardly from said housing so as to allow predetermined placement on the patient's body of said individual electrode spaced apart relative to said housing.

5. The electrode patch of Claim 4, wherein said housing member is adjustably extendable from said housing.

6. The electrode patch of Claim 4, wherein said housing member is pivotably connected to said housing.

7. The electrode patch of Claim 1, further comprising a hardwire connector for transmitting the processed digital signal by wire as a backup to wireless.

8. The electrode patch of Claim 1, wherein said housing is constructed from a plurality of laminated layers comprising woven material and plastic.

9. The electrode patch of Claim 1, wherein said at least one electrode comprises an electrically conductive gel.

10. The electrode patch of Claim 1, wherein said circuit board comprises an activation switch allowing a patient to manually activate the electrode patch.

11. The electrode patch of Claim 1, wherein said transmitter further comprises a transceiver for transmitting and receiving wireless signals.

12. The electrode patch of Claim 11, wherein said transceiver further comprises an antenna filter for filtering radio interference.

13. The electrode patch of Claim 1, further comprising a light source connected to said circuit board to provide a visual indication of electrode patch activation.

14. The electrode patch of Claim 1, wherein said power source comprises a relatively flat, compact disposable battery.

15. An apparatus for wireless monitoring of at least one electrical signal from a patient's body, said apparatus comprising in combination:

a disposable electrode patch having a relatively thin and flexible sealed housing disposed with an adhesive effective for releasably adhering said patch to the patient, a power source positioned in said housing for providing power, a printed circuit board positioned in said housing connected to said power source for thereby distributing power, a plurality of electrodes connected through said circuit board and positioned spaced apart in said housing so as to detect the electrical signal when the patch is properly adhered to the patient's body, a converter positioned in said housing connected through said circuit board to said plurality of electrodes for converting a detected electrical signal from the patient's body to a digital signal, a processor having a clock and positioned in said housing connected through said circuit board to said converter for processing the digital signal responsive to time, and a transmitter having a relatively flexible antenna and positioned in said housing connected to said processor through said circuit board for transmitting the processed digital signal as a wireless signal; and

a monitoring unit comprising a power source, a transceiver in wireless communication with at least said electrode patch, a global positioning receiver, a processor programmed at least to control the apparatus and to process signals received, at least one

communication port for external communications, and a display connected to said processor to visually display information from signals processed thereby.

16. The electrode patch of Claim 15, wherein said monitoring unit further comprises an activation switch for manually activating said apparatus.

17. The electrode patch of Claim 15, wherein said monitoring unit is sized so as to be portable by a patient wearing said electrode patch.

18. The electrode patch of Claim 15, wherein said monitoring unit further comprises a plurality of light sources connected to function as visual indicators of apparatus status.

19. The electrode patch of Claim 15, wherein said at least one communication port in said monitoring unit further comprises a plurality of communication ports.

20. The electrode patch of Claim (above), wherein at least one communication port of said plurality of communication ports comprises an RS-232 port.

21. The electrode patch of Claim (above), wherein at least one communication port of said plurality of communication ports is responsive to infrared light.

22. The electrode patch of Claim 15, wherein said monitoring unit power source is rechargeable.

23. The electrode patch of Claim 15, wherein said monitoring unit power source is a rechargeable battery and further comprising a battery charger therefor.

24. The electrode patch of Claim 15, further comprising a speaker connected to provide an audible signal responsive to apparatus status.

25. The electrode patch of Claim 15, wherein said monitoring unit further comprises at least one scroll switch connected to allow a patient to scroll through information appearing on said display.

26. The electrode patch of Claim 15, wherein said monitoring unit is remotely programmable from a base station processor communicating therewith through at least one individual communication port of the plurality of communication ports.

27. A disposable electrode patch for monitoring of at least one electrical signal from a patient's body, said patch comprising:

a relatively thin and flexible sealed housing externally disposed with an adhesive effective for releasably adhering said patch to the patient, having an electrode docking port positioned on an undersurface of said housing for therein engaging an electrode, and having a plurality of manually actuated stops adjacent said electrode docking port for releasably securing an electrode therein engaged;

a power source positioned in said housing for providing power;

a printed circuit board positioned in said housing connected to said power source for thereby distributing power;

an electrode releasably engaged in said electrode docking port so as to detect and communicate through said circuit board the at

least one electrical signal when the patch is properly adhered to the patient's body;

a converter positioned in said housing connected through said circuit board to said electrode for converting the detected electrical signal from the patient's body to a digital signal;

a processor having a clock and positioned in said housing connected through said circuit board to said converter for processing the digital signal responsive to time;

a transmitter having a relatively flexible antenna and positioned in said housing connected to said processor through said circuit board for transmitting the processed digital signal as a wireless signal; and

a light source connected to provide a visual signal indicative of functional status of said electrode patch.

28. The electrode patch of Claim 27, in combination with a monitoring unit comprising a power source, a transceiver in wireless communication with at least said electrode patch, a global positioning receiver, a processor programmed to control the apparatus and to process signals received, at least one communication port for external communications, and a display connected to said processor for visually displaying information from signals processed thereby.

29. A patient kit for use by a patient requiring medical monitoring, said kit comprising:

a carrying case disposed with interior cushioning material having a plurality of cavities therein for containing kit components;

a packet containing a plurality of disposable electrode patches, each patch of the plurality comprising a relatively thin and flexible sealed housing disposed with an adhesive effective for releasably adhering said patch to the patient, a power source positioned in said

housing for providing power, a printed circuit board positioned in said housing connected to said power source for thereby distributing power, a plurality of electrodes connected through said circuit board and positioned spaced apart in said housing so as to detect the electrical signal when the patch is properly adhered to the patient's body, a converter positioned in said housing connected through said circuit board to said plurality of electrodes for converting a detected electrical signal from the patient's body to a digital signal, a processor having a clock and positioned in said housing connected through said circuit board to said converter for processing the digital signal responsive to time, and a transmitter having a relatively flexible antenna and positioned in said housing connected to said processor through said circuit board for transmitting the processed digital signal as a wireless signal;

a monitoring unit comprising a rechargeable power source, a transceiver in wireless communication with at least said electrode patch, a global positioning receiver, a processor programmed at least to control the apparatus and to process signals received, at least one communication port for external communications, and a display connected to said processor to visually display information from signals processed thereby;

a charger for said rechargeable power source; and

an instructional video recording containing instructions for the patient on proper use of kit components.

30. A system for monitoring a plurality of patients, said system comprising:

a plurality of patients each individual patient of the plurality wearing a disposable electrode patch having a relatively thin and flexible sealed housing disposed with an adhesive effective for releasably adhering said patch to the patient, a power source

positioned in said housing for providing power, a printed circuit board positioned in said housing connected to said power source for thereby distributing power, a plurality of electrodes connected through said circuit board and positioned spaced apart in said housing so as to detect the electrical signal when the patch is properly adhered to the patient's body, a converter positioned in said housing connected through said circuit board to said plurality of electrodes for converting a detected electrical signal from the patient's body to a digital signal, a processor having a clock and positioned in said housing connected through said circuit board to said converter for processing the digital signal responsive to time, and a transmitter having a relatively flexible antenna and positioned in said housing connected to said processor through said circuit board for transmitting the processed digital signal as a wireless signal, each individual patient of the plurality also wearing a monitoring unit comprising a power source, a transceiver in wireless communication with said disposable electrode patch, a global positioning receiver, a processor programmed at least to control the apparatus and to process signals received, at least one communication port for external communications, and a display connected to said processor to visually display information from signals processed thereby; and

a base station processor comprising a transceiver in wireless communication with each individual monitoring unit worn by the plurality of patients so as to receive therefrom the signals processed, and a display for displaying information contained in the received signals, including patient location information received from said global positioning system receiver.

31. A system for wirelessly monitoring a plurality of patients, said system comprising:

a plurality of patients wherein each individual patient of the plurality has associated therewith a medical monitor which collects biometric information from said patient and includes a converter to convert collected biometric information to a digital signal, a processor for processing the digital signal, and a wireless transceiver for wirelessly transmitting the digital signal comprising the biometric information; and

a central processor receiving the transmitted digital signal for further processing and having a display for displaying the biometric information contained in a received signal.

32. The system of Claim 31, further comprising a plurality of processors in communication with said central processor through a network to thereby access the biometric information.

33. The system of Claim 31, further comprising a cellular wireless network for receiving from said medical monitor the wirelessly transmitted digital signal and forwarding said signal to said central processor.

34. The system of Claim 31, wherein said central processor comprises data storage for archiving received biometric information.

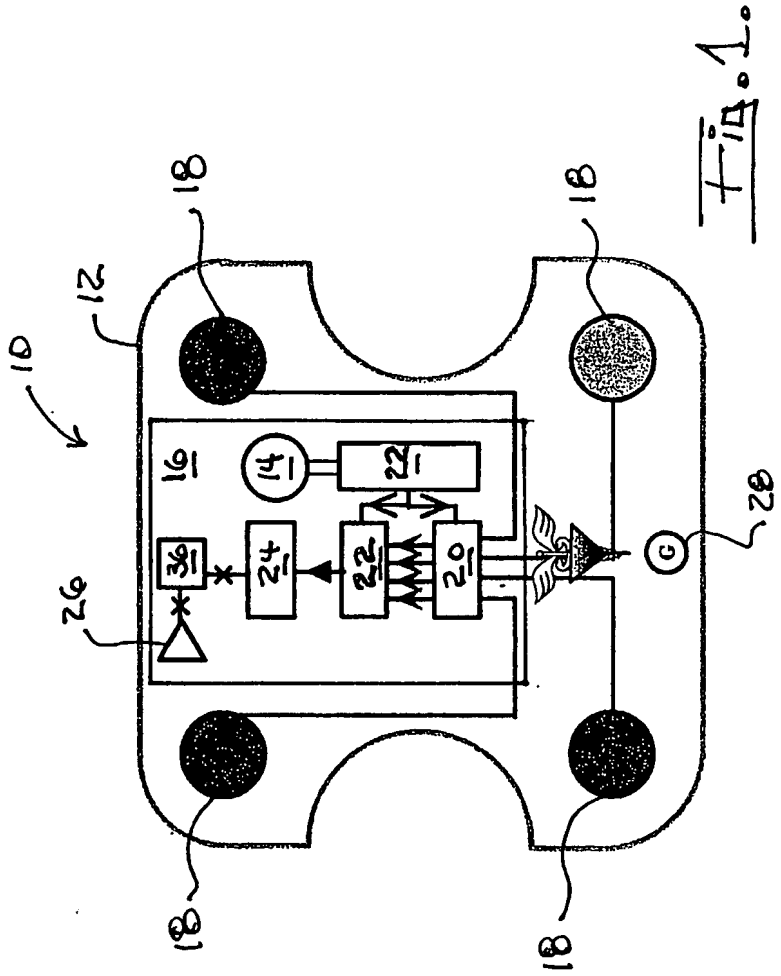

Fig. 1.

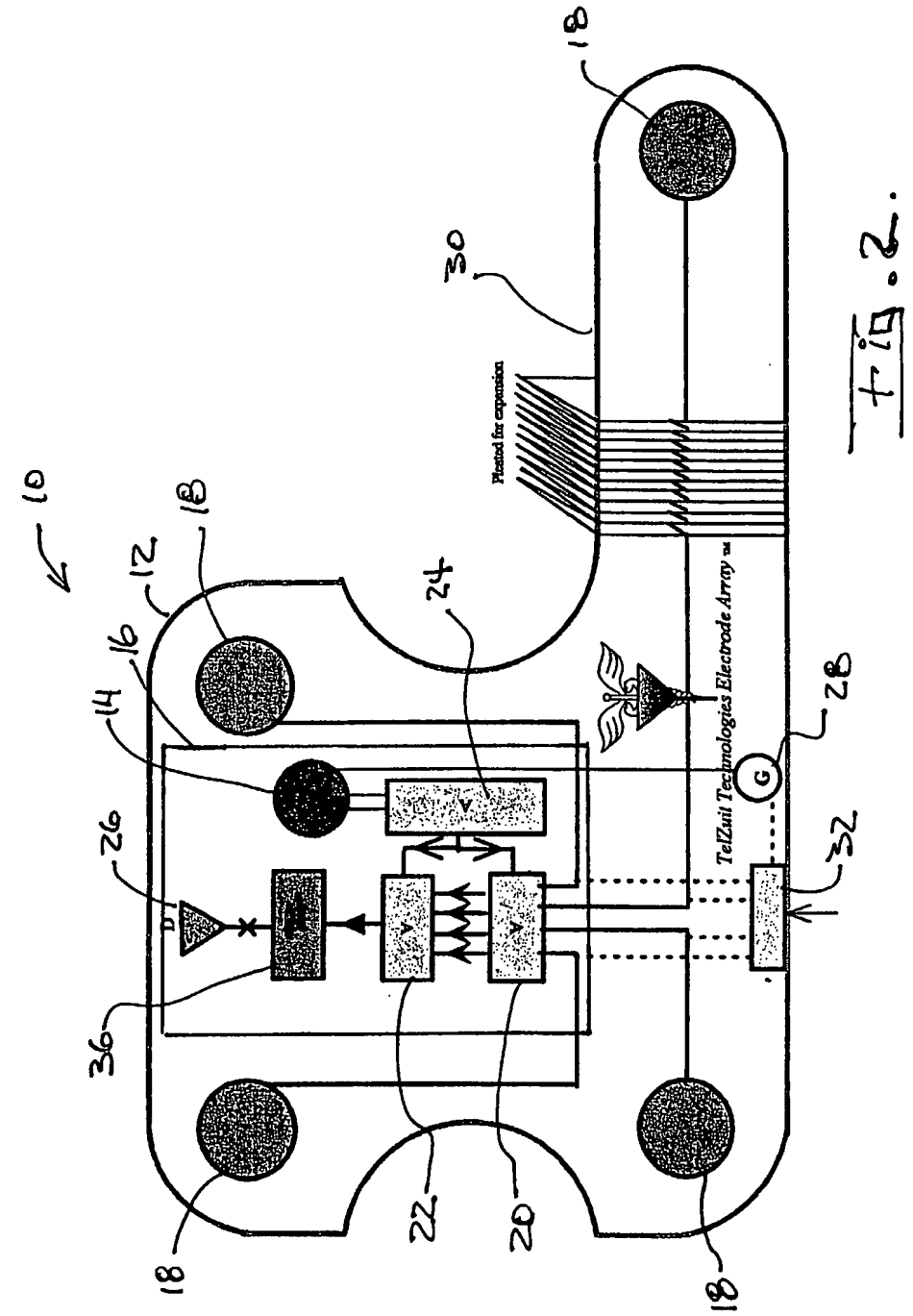
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Fig. 2.

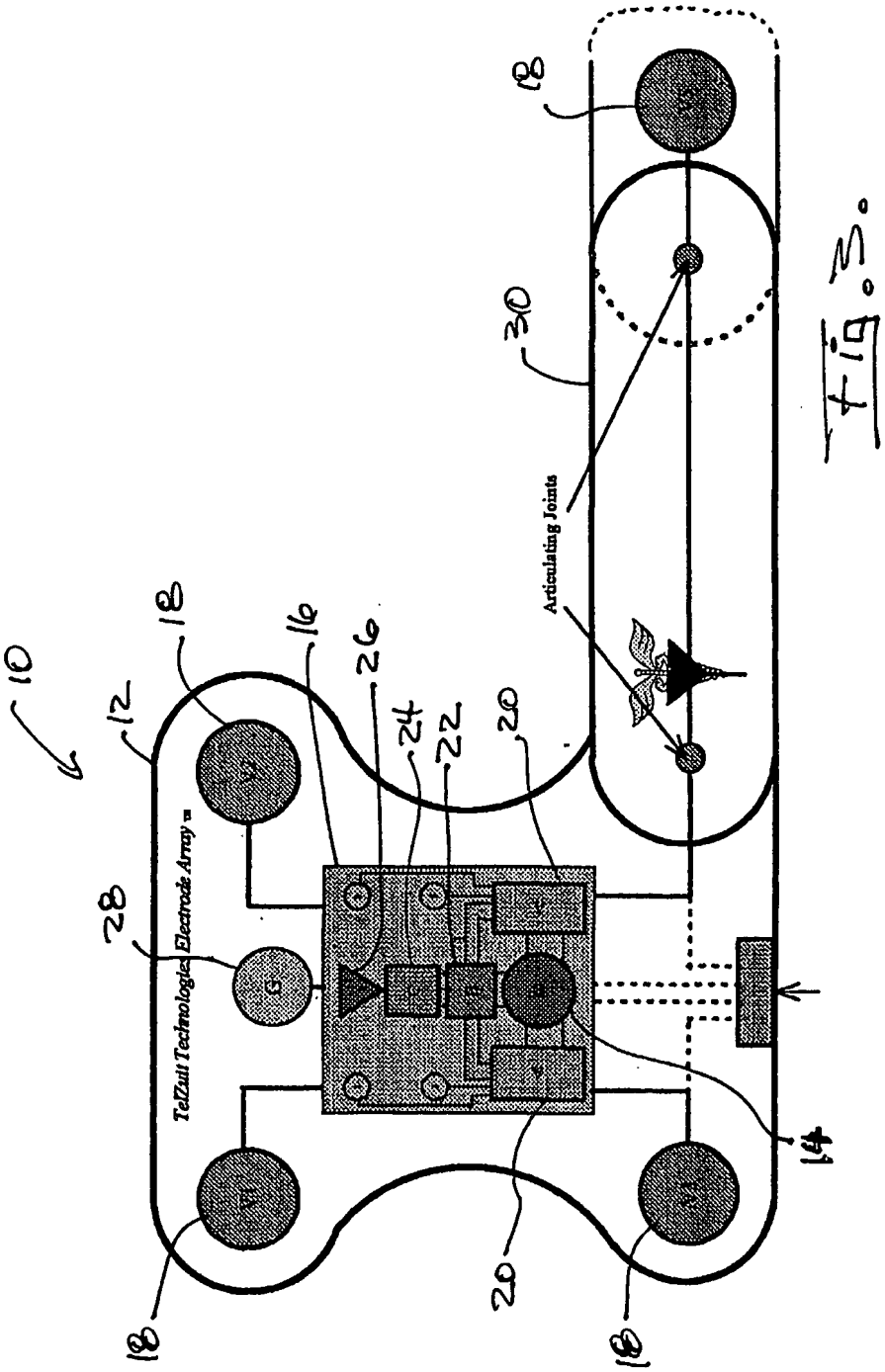
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Fig. 3.

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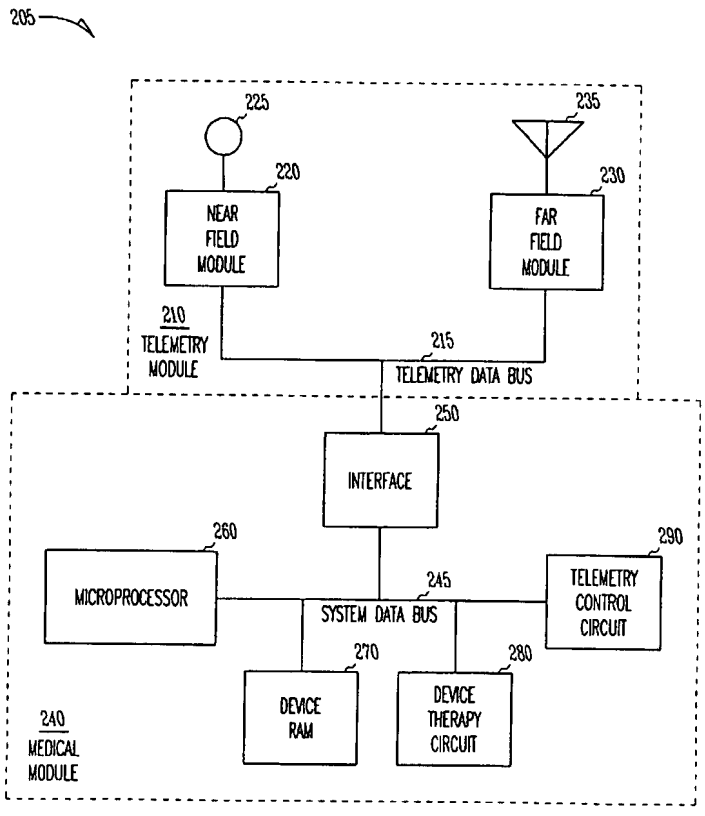
(54) Title: IMPLANTABLE MEDICAL DEVICE WITH TWO OR MORE TELEMETRY SYSTEMS



(57) Abstract: A telemetry system enabling radio frequency (RF) communications between an implantable medical device and an external device, or programmer, in which the RF circuitry is normally maintained in a powered down state in order to conserve power. At synchronized wakeup intervals, one of the devices designated as a master device powers up its RF transmitter to request a communications session, and the other device designated as a slave device powers up its RF transmitter to listen for the request. Telemetry is conducted using a far field or near field communication link.

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IMPLANTABLE MEDICAL DEVICE WITH TWO OR MORE TELEMETRY SYSTEMS

Technical Field

In general, the present subject matter relates to implantable medical devices, such as cardiac pacemakers and cardioverter/defibrillators, and in particular, the present subject matter relates to wireless telemetry with implantable medical devices.

Background

Implantable medical devices, including cardiac rhythm management devices such as pacemakers and implantable cardioverter/defibrillators, typically have the capability to communicate data with a device called an external programmer, or programmer, via a radio frequency telemetry link. A clinician may use such a programmer to program the operating parameters of an implanted medical device. For example, the pacing mode and other operating characteristics of a pacemaker may be modified after implantation in this manner. Modern implantable medical devices also include the capability for bidirectional communication so that information can be transmitted to the programmer from the implanted device. Among the data which may be telemetered from an implantable medical device are various operating parameters and physiological data, the latter either collected in real-time or stored from previous monitoring operations.

Telemetry systems for implantable medical devices may utilize radio frequency (RF) energy to enable bidirectional communication between the implantable medical device and an external programmer. In some applications, a wireless RF carrier is modulated with digital information, typically by amplitude shift keying where the presence or absence of pulses in the signal constitute binary symbols or bits. An exemplary telemetry system for an external programmer and a cardiac pacemaker is described in U.S. Patent No. 4,562,841, issued to Brockway et al. and assigned to Cardiac Pacemakers, Inc., the disclosure of which is incorporated herein by reference. The external

programmer transmits and receives the radio signal with an antenna incorporated into a wand that can be positioned in proximity to the implanted device. The implantable medical device also generates and receives radio signals by means of an antenna, which may include a wire coil inside of the device casing.

Some RF telemetry systems used for implantable medical devices, such as cardiac pacemakers, utilize inductive coupling between the antennas of the implantable medical device and an external programmer in order to transmit and receive wireless signals. Because the induction field produced by a transmitting antenna falls off rapidly with distance, such systems require close proximity between the implantable medical device and a wand antenna of the external programmer in order to work properly, usually on the order of a few inches. This requirement is inconvenient for the patient and the clinician, and thereby limits the situations in which telemetry can take place.

Summary of the Invention

The present invention includes a system and method for managing the duty cycles of RF telemetry components in an implantable medical device and an external device in order to lessen power consumption. In accordance with the invention, the RF telemetry circuitry of both devices is maintained in a quiescent or powered down state and powered up at predetermined time intervals. According to one embodiment, in a powered down state, the electric current is reduced and in a powered up state, the electric current is raised to allow reception or transmission of RF energy.

One of the devices is designated as the master device and configured to transmit a digital key when the RF circuitry is powered up in an attempt to establish a communications session with the other device. The other device is designated as the slave device and configured to listen for the digital key when its RF circuitry is powered up and transmit a response if the digital key is received. A communications session is then begun, and the circuitry of both devices remains powered up until the session is finished. When no communications sessions are taking place, the duty cycle of the RF circuitry in each device is thus reduced to only the time spent in transmitting or listening for the digital signature. In a preferred embodiment, the external device is

configured as the master device while the implantable medical device is configured as the slave device.

In addition, the present subject matter includes, among other things, a system having an implantable medical device having multiple means for wireless communication. In one embodiment, the system communicates using two independent means, each adapted for a particular function. For example, one embodiment includes a near field wireless communication means, such as an inductive coupling, as well as a far field wireless communication means, such as a far field RF coupling.

The present subject matter includes, among other things, an apparatus and method for enabling communications with an implantable medical device utilizing a near field inductive coupling and far field electromagnetic radiation. In one embodiment, communications in a clinical setting may be conducted using either the inductive coupling or the far field radiation coupling. Communications over a greater distance, in general, are conducted using the far field radiation coupling.

In accordance with one embodiment, a conductor coupled to the implantable medical device serves as an antenna that transmits and receives far field RF radiation modulated with telemetry data. The antenna is adapted to transmit far field radiation at a particular frequency. In one embodiment, a tuning circuit is used to adjust the impedance, and thereby tune the antenna to a particular frequency. In one embodiment, a therapy lead of a cardiac rhythm management device, which is otherwise used for stimulating or sensing electrical activity in the heart, has, incorporated therein, a wire antenna. In one embodiment, a specialized structure is incorporated into such a therapy lead in order to isolate a separate antenna section therein. In one embodiment, the antenna includes a helix structure located proximate to, or internal to, a housing of the medical device. In one embodiment, the antenna includes a wire disposed around the circumference of the outer surface of the device housing.

In one embodiment, a near field coupling includes an implanted coil of wire. The implanted coil is tailored and aligned for inductive coupling with an

external coil. In one embodiment, the coils are coupled by electromagnetic coupling.

In one embodiment, the system includes a timer function that allows far field communications to be enabled for a limited duration. In one embodiment, for example, a clinician marks the beginning of a programming period by transmitting a near field signal using a programmer wand. During the programming period, the far field section of the implantable medical device is engaged, and powered, and can receive programming instructions without using a wand. At the expiration of the programming period, the far field section is disabled. In one embodiment, the near field section remains continuously available and operates independent of the far field section. In one embodiment, the data received by the far field section is installed and executed immediately after receipt. In one embodiment, after transmitting updated parameters or program instructions, the clinician then uses the near field section to transmit an update command which causes the implantable medical device to implement the replacement parameters or program instructions.

Upon receiving an update command at the implantable medical device, the received data is transferred from a first memory location to a second memory location. Instructions, or data, stored in the second memory location controls the operation of the implantable medical device. For example, configuration statements or data can be communicated to the implantable medical device and initially stored in a temporary memory location and after receiving an update command, the contents of the temporary location are transferred to a semi-permanent memory location for execution and implementation.

In one embodiment, the near field communication section is used to signal to the implantable medical device that selected functions are available. In various embodiments, the selected functions include interrogation functions or programming functions. For example, in one embodiment, the implantable medical device transmits status information according to a predetermined schedule. In various embodiments, the status information is transmitted using either the far field transmitter, the near field transmitter, or both. In one embodiment, the far field receiver section normally remains in an unpowered

mode and after receiving a near field transmission, the far field receiver is powered and data received is stored in a memory. In one embodiment, the far field receiver is ordinarily unpowered and transitions to a powered mode upon receipt of a near field signal. The receipt of the near field signal marks the beginning of a period during which a predetermined programming or interrogation function is available. During the period before receiving the near field signal, and during the period after the predetermined period, the programming or interrogation function is not available.

Other means of programming, interrogating and communicating with the implantable medical device are also contemplated. For example, in one embodiment, a far field communication including a particular message marks the opening of a window during which both far or near field communications may be subsequently conducted.

As another example, one embodiment includes an implanted medical device having a far field transceiver operated according to a predetermined duty cycle and a programmer having a complementary far field transceiver, also operated according to a predetermined duty cycle. In such an embodiment, the medical device and the programmer are configured to communicate on a peer-to-peer basis and not on the basis of a master-slave relationship. In one embodiment of the peer-to-peer system, the medical device and the programmer are cycled in phase according to a predetermined schedule. In one embodiment, the medical device is operated according to a first duty cycle and the programmer is operated according to a second duty cycle or operated continuously.

Brief Description of the Figures

Fig. 1 is a block diagram of a telemetry system for an implantable medical device and an external device.

Fig. 2 is a block diagram view of an embodiment of an implantable medical device having both a near field module and a far field module.

Fig. 3 is a block diagram of an embodiment of an implantable medical device having a near field transceiver and a far field transmitter.

Fig. 4 is a block diagram of an embodiment of an implantable medical device having a near field transceiver and a far field receiver.

Fig. 5 is a block diagram of an embodiment of an implantable medical device having a near field transceiver and a far field transceiver.

Fig. 6 is a flow chart illustrating a method of transmitting executed by an embodiment of the present subject matter.

Fig. 7 is a flow chart illustrating a method of communicating executed by an embodiment of the present subject matter.

Fig. 8 is a block diagram of a programmer in accordance with the present subject matter.

Fig. 9 is a block diagram of an embodiment of an implantable medical device having a far field transceiver.

Detailed Description

The present invention includes a system and method for providing far-field RF telemetry between an implantable medical device and an external device in which power consumption is lessened by managing the duty cycles of the RF transmitting and receiving components. As used herein, the term data includes digital data and analog signals.

Fig. 1 shows selected telemetry components of external device 200 and implantable medical device 100. In this functional block diagram, the components are shown as being substantially identical in each device, however, in one embodiment, the components differ. In this exemplary embodiment, implantable medical device 100 and external device 200 are microprocessor-based devices with implantable medical device 100 having controller 102A and external device 200 having controller 102B. Controllers 102A and 102B each include a microprocessor and memory for data and program storage that supervises overall device operation as well as telemetry. In one embodiment, the code executed by controllers 102A and 102B also implements the duty cycle management schemes to be described below. Implantable medical device 100, in one embodiment, includes a cardiac rhythm management device such as a pacemaker or implantable cardioverter/defibrillator, and external device 200 includes a data-gathering device such as an external programmer or remote monitor. In one embodiment, both device 100 and device 200 are battery powered. In one embodiment, device 200 is powered by a metered line service.

In one embodiment, long-range RF receivers 120A, and 120B, and long-range RF transmitters 110A, and 110B, are interfaced to microprocessors 102A, and 102B, in implantable medical device 100 and external device 200, respectively. In one embodiment, transmitters 110A, and 110B, and receivers 120A, and 120B, are coupled to antennas 101A, and 101B, through transmit/receive switches 130A and 130B, respectively. Switches 130A and 130B are controlled by controllers 102A and 102B, respectively. Switch 130A passes RF signals from transmitter 110A to antenna 101A or from antenna 101A to receiver 120A. Switch 130B passes RF signals from transmitter 110B to antenna 101B or from antenna 101B to receiver 120B. To effect communications between devices 100 and 200, an RF carrier signal modulated with digital data is transmitted wirelessly from one antenna to the other. In one embodiment, a demodulator for extracting digital data from the carrier signal is incorporated into receivers 120A and 120B, and a modulator for modulating the carrier signal with digital data is incorporated into transmitters 110A and 110B. In one embodiment, an interface coupled to controller 102A and RF transmitter 110A, and controller 102A and receiver 120A in device 100 enables data transfer and also provides a means by which controller 102A can power up or power down receiver 120A or transmitter 110A and thus manage duty cycles in the manner described below. In one embodiment, an interface coupled to controller 102B and RF transmitter 110B, and controller 102B and receiver 120B in device 200 enables data transfer and also provides a means by which controller 102B can power up or power down receiver 120B or transmitter 110B and thus manage duty cycles in the manner described below. In one embodiment, wakeup timers 180A and 180B are coupled to controllers 102A, and 102B, respectively. Timers 180A and 180B define the duty cycles and, in one embodiment, are implemented in code executed by the respective controller and, in one embodiment, include discrete components.

Far field telemetry over greater distances can be achieved by wireless RF communication. The ability to communicate over a greater distance may be advantageous for the patient as well as the clinician. The increased communication range makes possible other applications of the telemetry system

such as remote monitoring of patients and communication with other types of external devices. To emit a substantial portion of the energy delivered to an antenna as far field radiation, preferably, the wavelength of the driving signal is not much larger than the length of the antenna. Far-field radio frequency communications with an antenna of a size suitable for use in an implantable medical device therefore can be conducted using a carrier frequency in the range between a few hundred MHz to a few GHz. Active transmitters and receivers for this frequency range employ special RF components (which may include SiGe or GaAs semiconductor devices) that consume a significant amount of power (typically tens of milliwatts). Implantable medical devices, however, are powered by a battery contained within the housing of the device that can only supply a limited amount of continuous power before it fails. When the battery fails in an implantable medical device, it must be replaced which necessitates a reimplantation procedure. Portable external devices may also be battery powered, and recharging or replacement of the battery in such devices is an inconvenience.

Long-range RF telemetry circuitry (i.e., the transmitter and receiver) typically requires power on the order of tens of milliwatts in order to operate. Cardiac rhythm management devices in use today, on the other hand, are usually designed to operate with average power in the microwatt range. Thus, to meet the power budget of such devices, the RF telemetry circuitry is preferably duty cycled down by about four orders of magnitude. An example of duty cycling for an implantable medical device is described in U.S. Patent No. 5,342,408, presently assigned to the Guidant Corp. and hereby incorporated by reference. External devices, although not subject to the same power constraints as implantable medical devices, may be portable and battery powered. Duty cycling down the RF circuitry in external devices may advantageously avoid the inconvenience of premature battery depletion. In one embodiment, implantable medical device 100 employs a power management scheme in which RF receiver 120A and RF transmitter 110A are duty cycled based upon synchronized timer wakeups. In one embodiment, external device 200 employs a power

management scheme in which RF receiver 120B and RF transmitter 110B are duty cycled based upon synchronized timer wakeups.

In such a scheme, the RF telemetry circuitry is normally in a low power state until powered up to transmit or receive a message. In one embodiment, the controller in the implantable medical device and the controller in the external device are both programmed to maintain the RF circuitry in a quiescent or powered down state and then power up the circuitry at programmable time intervals based upon timer expirations or other conditions.

In one embodiment, one of the devices is designated as the slave device. After a programmable wakeup time interval, the RF receiver in the slave device is powered up for a specified slave time window and listens for a valid digital key transmitted by another device designated as the master device. The master device, after a programmable wakeup time interval, also powers up its RF transmitter and receiver for a specified master time window to transmit the digital key and listen for a response from the slave device. If no valid digital key is received, the slave device powers down the RF receiver until the next wakeup interval. If a valid digital key is received, the slave device powers up its RF transmitter and responds by transmitting a response code to the master device to initiate a communications session.

In one embodiment, the slave device receives a digital key without initiating a communications session, in which case the reception of the key is used for timing or other purposes by the slave device. In one embodiment, different digital keys are used to differentiate between situations where the slave is obligated to respond and initiate a communications session with the master device and situations where the slave has the option to respond or not. If a communications session is established, the RF circuitry in both the slave and master devices remains powered up until the session is finished, and then the RF circuitry in each device is powered down until the next wakeup interval.

In one embodiment, the external device is configured as the master device while the implantable medical device is configured as the slave device. This configuration may be less burdensome on the implantable medical device's more limited battery power supply since periodically powering up the RF

receiver to listen for a digital key may draw less current than powering up both the RF transmitter and RF receiver to transmit a digital key and listen for a response. In addition, in certain situations, it may be undesirable for the implantable medical device to transmit an RF signal. For example, a patient may be onboard a commercial airplane or in a country where regulations prohibit RF transmissions at the system frequency. If the implantable medical device is the slave, then unless a digital key is received, the implantable medical device will not broadcast an RF transmissions.

In one embodiment, the programmable wakeup time intervals for the master and slave devices are synchronized so that they occur simultaneously. As long as the devices are located within range, a communications session would then be established at every such wakeup interval.

In one embodiment, synchronization of the wakeup timers is performed during any communications session established with the RF telemetry link. Synchronization can be done by a variety of means. In one embodiment, synchronization entails having one device transmit a time stamp and having the other device adjust its timer accordingly. In one embodiment, the receiving device synchronizes by detecting a start of a message and realigning its wakeup interval to begin at the same time. In one embodiment, synchronization of the timers is performed using inductive coupling. In one embodiment, an inductively coupled link is used to transmit a magnetic pulse that activates a switch or is otherwise detected by the receiving device, and the device is then programmed to synchronize its wakeup timer at that time by setting it to a predetermined value.

Another alternative is for a communications session to be established with an inductively coupled link such as used in conventional short-range telemetry. Fig. 1 shows inductively coupled transceivers 140A and 140B, each coupled to antennas 150A and 150B, respectively, for each of the implantable medical device and external device. Transceivers 140A and 140B, and antennas 150A and 150B, draw low power, and in one embodiment, are operated continuously. In this manner, a communications link can be established immediately without waiting for a wakeup interval.

Whatever means are used to establish a communications session, the wakeup timers of the master and slave devices can be synchronized and a programmable wakeup interval agreed upon by the two devices during the session. The wakeup interval can be a fixed value set by clinician input or can be made to vary in accordance with detection of particular events. For example, when the implantable medical device includes a cardiac rhythm management device and an arrhythmia is detected, the implantable medical device can be programmed to increase the frequency at which communications sessions occur in order to more closely monitor the patient. This is accomplished by the implantable medical device reducing the wakeup interval for each device when a communications session with an external device is next established.

In one embodiment, the frequency of communications sessions is increased by reducing the wakeup interval when the implantable medical device detects a low battery condition or a change in lead impedance. Increasing the frequency of communication sessions allows the operating status of the implantable medical device to be more frequently communicated to the external device. In one embodiment, clinician input from an external programmer can be used to change the wakeup interval of the implantable medical device. In one embodiment, the wakeup interval is varied pseudo-randomly from one communications session to another. Pseudo-random variability may be desirable in order to minimize the chance of periodic interference from an external source or other devices causing transmission problems.

In one embodiment, each slave device has a unique digital key and a single master device can thus, individually, access each slave. This configuration prevents two slave devices from interfering with each other by responding to a digital key transmitted from the master device. In one embodiment, a slave device is programmed to respond to a digital key used in common with one or more other devices. For example, in one embodiment, a digital key is uniquely specified for a family of slave devices. In that case, the possibility of interference can be lessened by programming the slave device to respond to a digital key after a random delay time.

In one embodiment, the timing of the master device is perfectly synchronized with the timing of the slave device. That is, the power up times for the receiver in the slave device and both the transmitter and receiver of the master device are precisely defined. Precise definition of the power up times allows the duty cycles of the RF circuitry to be minimized, thus reducing power consumption.

It may be found that timing drift prevents perfect synchronization of the wakeup intervals. In one embodiment, the master time window begins at some time before the slave time window starts. That is, the master device begins transmitting the digital key shortly before the slave device is expected to be listening for it. In one embodiment, the master time window extends beyond the slave time window such that if no response from the slave is received, the master continues transmitting the digital key until after the slave is expected to no longer be listening. In one embodiment, the listening time of the slave or slave time window is great enough to receive at least two digital keys so that if it just misses the start of a key transmitted by the master, the next transmitted key will be received in its entirety. This technique thus increases the probability that communication between the devices will be established even when timing drift occurs. Because the master device transmits and receives for a longer period of time than the slave device listens, there is a greater energy burden on the master device. In one embodiment, the implantable medical device, with its more severe battery constraints, is configured as the slave device.

In one embodiment, the wakeup timers are synchronized (or resynchronized) automatically during each communication session. Resynchronizing during each communication session reduces the amount of desynchronization that exists between the timers of the master and slave devices (due to timing drift). In one embodiment, the device receiving the time stamp attempts to compensate for the amount of drift that occurred since the last communications session. At each such session, the device receiving the time stamp stores the amount by which it had to adjust its wakeup timer and thus learns the average amount of timer drift that occurs between the timers of both devices. The device is programmed to set its wakeup timer either ahead or

behind that of the wakeup timer of the other device if it was slow or fast, respectively, relative to that timer. The amount by which the timer is set ahead or behind that of the other timer can be made either equal to the amount of drift or some fraction of it.

In one embodiment, the master device adjusts the time window used to transmit the digital key and listen for a response at each wakeup interval based on the average amount of timer drift. In one embodiment, the master device adjusts the time window based on the time since the last resynchronization. In one embodiment, the master device begins transmitting the digital key before it anticipates that the slave device will be listening for it, and continues transmitting the key until after it anticipates that the slave device has powered down its receiver. This helps to ensure that the master device will catch the slave device listening even if the timers of the two devices have drifted relative to one another. The amount of drift between the two wakeup timers will increase as a function of the time since the last resynchronization. The amount of energy that the master device spends in attempting to establish a communications session can therefore be reduced by making the duration of the transmitting and listening time window a function of the time since the last resynchronization.

Consider the following example. Assume that the wakeup timers of the master and slave devices were last resynchronized 100 seconds ago. At the next wakeup interval, the master device could anticipate that the drift of the wakeup timers would be rather small, and therefore, the master device can reliably begin sending the digital key to the slave device only a few tens of microseconds before it anticipates that the slave will be listening. On the other hand, if the wakeup timers of the master and slave devices were last resynchronized eight hours (28,800 seconds) ago, then it is likely that the drift will be 288 times greater than had it been resynchronized 100 seconds ago. Thus, at the next wakeup interval, the master device should begin sending the digital key to the slave device a few tens of milliseconds before it anticipates that the slave will be listening.

In one embodiment, the master device is configured to conduct a search for a non-synchronized slave receiver. A slave receiver may be non-synchronized for any of a number of reasons. For example, but not by way of limitation, the slave receiver may be newly implanted in a particular patient, the batteries of the master device may have just been changed, or the master device may not have been used recently. In one embodiment, the master and slave devices are resynchronized using an inductive telemetry link as described above.

Consider an example where the master device has not successfully established a communications session with a particular slave device for a specified maximum period of time (e.g., 4 hours). In this case, the master device will assume that the slave device is not synchronized, and the master device will begin a non-synchronized receiver search. In one embodiment, the master device continuously transmit its digital key and listen for a response until either a communications session is established or a programmable maximum non-synchronized search interval (e.g., 200 seconds) passes. If a communications session is established, the wakeup timers of the two devices are resynchronized. If the maximum non-synchronized search interval passes with no communications session being established, then the master device assumes that no slave device is within range and goes back to its previous wakeup interval pattern. If the specified maximum time with no communications session being established again passes (e.g., another 4 hours), the non-synchronized receiver search is repeated. In one embodiment, the master device keeps track of the expected slave device wakeup windows during a non-synchronized receiver search so that the master device can return to these if no non-synchronized slave device is found.

In the systems described above, the RF circuitry of both the implantable and external devices are duty cycled in order to lessen power consumption, with one device operating as a slave and the other device operating as a master. In one embodiment, the devices are programmed such that one device is always configured as the master device while the other device is programmed to always be configured as the slave device. In one embodiment, the devices are programmed to dynamically configure themselves as either master or slave

devices depending upon circumstances. For example, in one embodiment, both the implantable and external devices are programmed to normally act as slave devices such that they both wake up at periodic intervals to listen for a communications session request from the other device. Upon a change in circumstances, such as clinician input to the external device or detection of a particular event by the implantable medical device, one of the devices configures itself as a master to request a communications session at the next wakeup interval. In order to deal with the situation where both devices configure themselves as master devices, in one embodiment, the system incorporates a mediation scheme like those employed in peer-to-peer networks.

In one embodiment, the RF circuitry of the master device is duty cycled and that of the slave device is continuously powered. In one embodiment, the RF circuitry of the slave device is duty cycled and that of the master device is continuously powered. Such a configuration may be beneficial, for example, if one device has unusually severe battery constraints or is intended for very limited use while the other device has access to continuous power. In such a system, the duty cycled device is configured to operate as either a master or slave device in establishing communications sessions with the continuously powered up device. In one embodiment, the duty cycled device is configured as a slave in order to lessen its power requirements somewhat. The continuously powered device, acting as a master, then periodically powers up its RF circuitry at programmed wakeup intervals in order to attempt to initiate a communications session with the duty cycled device.

Fig. 2 illustrates an embodiment of an implantable medical device 205 having telemetry module 210 coupled to medical module 240. In one embodiment, implantable medical device 205 is housed in a sealed canister suited for implantation in a human body. Telemetry module 210 includes near field module 220 and far field module 230. Near field module 220 and far field module 230 are coupled together by telemetry data bus 215. In various embodiments, bus 215 includes a digital data bus or an analog signal line. Near field module 220 is coupled to antenna 225, herein depicted by a loop, or coil. In one embodiment, antenna 225 includes an inductive loop. Far field module 230

is coupled to antenna 235, herein depicted by an RF antenna. In one embodiment, antenna 235 includes a dipole antenna. In one embodiment, antenna 235 includes a monopole antenna.

Antenna 235 may include a circumferential antenna disposed around an exterior surface of the device housing. Circumferential antenna structures are described in co-assigned U.S. Patent application serial number 09/921,653, filed August 3, 2001, CIRCUMFERENTIAL ANTENNA FOR AN IMPLANTABLE MEDICAL DEVICE, and incorporated herein by reference in its entirety.

Near field module 220, in one embodiment, includes an inductively coupled transmitter/receiver 140A, as described relative to Fig. 1. Far field module 230, in one embodiment, includes RF receiver 120A, RF transmitter 110A and T/R switch 130A, as described relative to Fig. 1. In one embodiment, antenna 225 includes the structure described relative to antenna 150A of Fig. 1. In one embodiment, antenna 235 includes the structure described relative to antenna 101A of Fig. 1. In one embodiment, a switch is provided to select, and therefore communicate using, either near field module 220 or far field module 230.

According to one embodiment, far field communications conducted by far field module 230 are preferably conducted using an industrial, scientific, medical (ISM) band. One ISM band is between approximately 902 and 928 MHz, however frequencies above or below this figure are also possible. At another ISM band of frequencies, approximately 2.45 GHz, the effects of tissue absorption may undesirably attenuate the far field signal, and thus, limit the effective communication range. In some regions of the world, such as for example, Europe, frequencies near 868 to 870 MHz SRD (short range device) band may be available and thus, in one embodiment the implantable medical device and external device communicate at a frequency of 869.85 MHz. In one embodiment, the far field communication frequency is at the Medical Implant Communications Service (MICS) band, between approximately 402 and 405 MHz.

Medical module 240 is coupled to telemetry data bus 215 by interface 250. In one embodiment, interface 250 includes telemetry direct memory access

(DMA) and data buffers. In the embodiment shown, interface 250 is coupled to system data bus 245. Bus 245 is further coupled to microprocessor 260, device random access memory (RAM) 270, device therapy circuit 280 and telemetry control circuit 290. In one embodiment, bus 245 includes a multiple conductor digital data bus. In one embodiment, microprocessor 260 includes the structure described relative to μP 102A and wakeup timer 180A of Fig. 1.

In various embodiments, microprocessor 260 includes a digital or analog processor adapted for managing data or signals on bus 245. Device RAM 270 provides storage for data or programming for execution by microprocessor 260. In one embodiment, device therapy circuit 280 includes a pulse generator or other therapeutic system. In one embodiment, therapy circuit 280 includes a monitoring circuit adapted for monitoring the condition or performance of an organ or other physiological parameter. In one embodiment, device therapy circuit 280 includes circuitry for monitoring the condition of implantable medical device 205. For example, in one embodiment, device therapy circuit 280 provides a signal based on remaining battery capacity to microprocessor 260. Telemetry control circuit 290 includes circuitry adapted for controlling telemetry functions relative to the modules coupled to telemetry data bus 215.

Figs. 3, 4 and 5 illustrate exemplary embodiments of implantable medical device 205, each of which includes a medical module 240 coupled to telemetry data bus 215 as previously described. For example, in Fig. 3, implantable medical device 205A is shown having near field transceiver 220A and far field transmitter 230A. In one embodiment, near field module 220 includes near field transceiver 220A. As a further example, Fig. 4 illustrates implantable medical device 205B having near field transceiver 220A and far field receiver 230B. In one embodiment, far field module 230 includes far field receiver 230B. As yet a further example, Fig. 5 illustrates implantable medical device 205C having near field transceiver 220A and far field transceiver 230C. In one embodiment, far field module 230 includes far field transceiver 230C. Other embodiments are also contemplated, such as, for example, a near field transmitter or receiver coupled to any of transmitter 230A, receiver 230B or transceiver 230C.

Consider next the operation of the present system. At the time of implantation, implantable medical device 205 may be programmed and controlled by a medical programmer, or external device, adapted to communicate using near field transceiver 220A. An embodiment of an external device is illustrated in Fig. 1. The programmer may include a flexible wand having a transceiver antenna that communicates with near field transceiver 220A. For example, in one embodiment, the programmer includes an inductive loop antenna and near field transceiver 220A also includes an inductive loop antenna. Following implantation of the device, subsequent programming and controlling may also be accomplished using near field transceiver 220A.

The embodiment illustrated in Fig. 3 allows implantable medical device 205A to transmit data using a far field transmission. For example, in one embodiment, the data includes operational conditions or parameters concerning implantable medical device 205A or the patient in which device 205A is implanted. In one embodiment, data is transmitted using far field transmitter 230A according to a schedule having a predetermined duty cycle or according to a programmed schedule. In one embodiment, data is transmitted using far field transmitter 230A upon the occurrence of a predetermined event or when a particular parametric value is exceeded. In one embodiment, data is transmitted using far field transmitter 230A in response to receiving a particular signal via near field transceiver 220A. In various embodiments, far field transmissions using transmitter 230A proceed until finished, for a predetermined period of time, or until a terminate signal is received via near field transceiver 220A.

The embodiment illustrated in Fig. 4 allows implantable medical device 205B to receive data using a far field transmission. For example, in one embodiment, the data includes programming information or parameters for implementation by implantable medical device 205B. The parameters may concern therapy for the patient in which implantable medical device 205B is implanted. In one embodiment, data is received using far field receiver 230B according to a schedule having a predetermined duty cycle or according to a programmed schedule. In one embodiment, data is received using far field receiver 230B upon the occurrence of a predetermined event or when a particular

parametric value is exceeded. In one embodiment, data is received using far field receiver 230B in response to receiving a particular signal via near field transceiver 220A. In various embodiments, far field transmissions received using receiver 230B proceed until finished, for a predetermined period of time, or until a terminate signal is received via near field transceiver 220A or far field receiver 230B.

The embodiment illustrated in Fig. 5 allows implantable medical device 205C to both receive data and transmit data using a far field transmission. For example, in various embodiments, far field received or transmitted data includes programming information or parameters for implementation by implantable medical device 205C, concerning device 205C, or the patient in which device 205C is implanted. The parameters may concern therapy for the patient in which device 205C is implanted. In various embodiments, data is transmitted or received according to a schedule having a predetermined duty cycle or according to a programmed schedule. In one embodiment, data is received or transmitted using far field communication upon the occurrence of a predetermined event or when a particular parametric value is exceeded. In one embodiment, data is communicated using far field transceiver 230C in response to receiving a particular signal via near field transceiver 220A. In various embodiments, far field communications proceed until finished, for a predetermined period of time, or until a terminate signal is received via near field transceiver 220A or far field transceiver 230C. Far field transceiver 230C includes a far field transmitter and a far field receiver and in one embodiment, the far field transmitter communicates using a communication protocol that differs from that of the far field receiver.

In various embodiments, the communication modules enable one or more modes of communicating. The plurality of communication modes may each have full redundancy or each may provide different capabilities. For example, in one embodiment, a first communication mode supports receiving operational parameters and a second communication mode transmits diagnostic data.

Fig. 6 illustrates a method implemented by one embodiment of the present system. In the figure, method 300 concerns the transmission of data

from an implantable medical device having a plurality of transmitters or transceivers. Beginning at 310, the method includes receiving or generating data at the implantable medical device, as noted at 320. For example, in one embodiment, data is received from electrodes or leads that terminate in various portions of the body and are coupled to the implantable medical device. In one embodiment, the data is processed by the implantable medical device and the results generated are stored and available for telemetering to a remote programmer. At 330, a transceiver is selected for transmitting the data to the remote programmer. In one embodiment, a transmitter is selected at 330. The selected transmitter, or transceiver, may include a near field transmitter, a far field transmitter, or a combination of near and far field.

Continuing with the figure, at 340, the selected transceiver is powered on. In one embodiment, the process of turning on the selected transceiver includes entering an "awake" mode after departure from a "sleep" mode. At 350, an outbound signal, including the digital data previously stored, is wirelessly transmitted by the transmitter. The process ends at 360. The process may also be performed in an order which differs from that illustrated.

Fig. 7 illustrates method 370 which may be useful in programming or configuring an implantable medical device. Beginning at 380, a near field signal is received as illustrated at 390. In one embodiment, the near field signal marks the beginning of a time period, or window, during which the far field communication capabilities of the implantable medical device are available. In one embodiment, during predetermined times after the window, communications are conducted using the far field communication capabilities of the device. Upon receiving a signal using the near field link, the far field window remains open. The duration of the time period is monitored by a timer and at 400, the timer is started. At 410, following the start of the timer, the far field transceiver is powered on or otherwise enabled. At 420, wireless communications between the implantable medical device and the remote programmer are conducted using the far field transceiver. At 430, data encoded in the received signal is stored in memory coupled to the implantable medical device and outbound data is stored in memory accessible to the external programmer. In various embodiments, the

data includes replacement programming or operating parameters that controls the operation of the implantable medical device. An inquiry as to the status of the timer occurs at 440 after which processing branches to 420 if the predetermined time period has not lapsed, or continues to 450 if the period has lapsed. At 450, the far field communication capabilities are terminated, and in one embodiment, this entails turning off power to the far field transceiver. The process ends at 460.

In one embodiment, the method illustrated in Fig. 7 includes checking for a terminate command in lieu of checking the timer for expiration. If a terminate command is received, either by the far field link or the near field link, then the far field transceiver is powered off. Otherwise, communications using the far field transceiver continues until receipt of a termination command. The termination command may save battery resources of the device by powering off the far field transceiver in advance of a signal from the timer.

Fig. 8 illustrates a programmer, or external device, in accordance with one embodiment of the present system. Programmer 500 includes near field module 520 and far field module 530, each coupled to microprocessor 560. Near field module 520 is coupled to antenna 525, here illustrated as a loop antenna suitable for inductive coupling. Far field module 530 is coupled to antenna 535, here illustrated as an antenna, and in various embodiments, includes a monopole or a dipole antenna. Microprocessor 560 is coupled to input/output module 575 and memory 570. In various embodiments, input/output module 575 includes a keyboard, bar code scanner, monitor, audio speaker, microphone, printer, storage media, wireless communication modules, or other device. In one embodiment, input/output module 575 provides an interface with which a human operator can communicate with an implantable medical device. Memory 570 provides storage for data and programming used by microprocessor 560. In one embodiment, memory 570 provides storage for data to be transmitted to, or received from, an implantable medical device.

In one embodiment, programmer 500 includes both a far field and near field communication module, as illustrated, with each module operating

independent of the other. In one embodiment, programmer 500 includes either a far field communication module or a near field communication module.

Exemplary System

By way of example, and not by way of limitation, an exemplary system is described as follows.

In this embodiment, an inductive coupling provides a near field communication link. The inductive coupling is continuously available since it draws little or no power when receiving and is able to receive power from an external programmer for purposes of operating the implantable medical device. In addition, the inductive coupling is adapted to convey recharging power to the battery of the implantable medical device. In various embodiments, the near field communication link includes an optical link, an audible link, or an infrared link.

In one embodiment, the far field communication link draws power at a rate that is greater than that of the near field link. Also, in one embodiment, transmitting a far field signal draws a greater instantaneous current than does receiving a far field signal, however, the far field transmissions are of such short duration that receiving far field transmissions draws a greater total power. Consequently, far field reception is available according to a duty cycle. By way of example, the ability to receive a far field transmission exists for a short period of time each minute.

The ability to communicate using a plurality of modes, such as a far field and near field mode, may provide advantages that are not otherwise available with a single communication mode. For example, the availability of a second communication mode increases the likelihood that the programmer and implantable medical device can communicate reliably. In situations where one mode of communication is unavailable, it may be that another communications mode is available. In addition, whereas the far field communications means may operate according to a duty cycle, the near field communications link is continuously available, and therefore, available on demand. Furthermore, in some regions of the world, the ability to conduct far field communications may

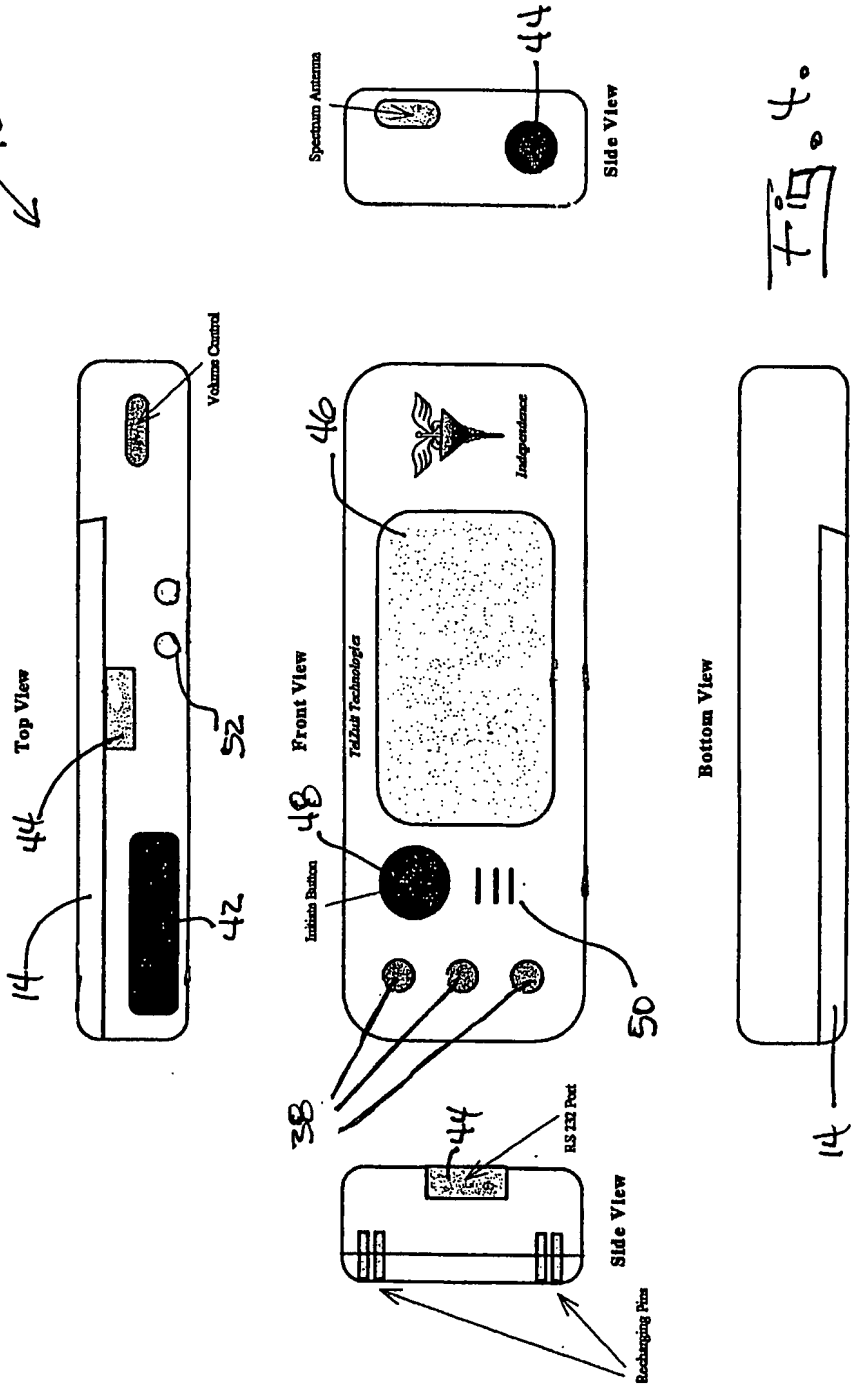
be restricted, and therefore, the availability of a near field link allows uninterrupted communications.

Using the far field communication link, one embodiment of the present system transmits a signal that may be translated as either "I'm OK" or "I'm not OK." In one embodiment, after receiving a "not OK" signal, the remote programmer commences a procedure whereby the patient, a doctor, or other responsible party, is contacted and, if warranted, the patient is invited to seek medical attention. Contacting the patient, doctor, or other responsible party may entail placing a telephone call, transmitting a pager message, sending an e-mail, broadcasting a radio message, or otherwise attempting to establish communications.

The present system also may find application in the operating room at the time of implantation of the medical device. For example, at the time of implantation, one embodiment allows using the far field link for initial configuration, diagnosis and set up procedures. Enhanced sterility, increased flexibility, and reduced burden are possible advantages achievable by reducing the reliance on the traditional programmer wand. Furthermore, one embodiment of the present system allows remote follow-up with the patient. This may reduce or eliminate the need for periodic visits to a clinic, thereby reducing system costs.

In one embodiment, security measures are implemented to assure that access to the implantable medical device is limited to authorized users. For example, in one embodiment, data transmitted from the implantable medical device is encrypted, or otherwise encoded, to restrict access. In one embodiment, encryption includes use of a key encryption system utilizing both a public key and a private key. In one embodiment, the implantable medical device is programmed to respond only to instructions from an authorized programmer. In one embodiment, the security system is implemented by means of a programming window of time that is triggered by an inductively coupled programmer wand.

In one embodiment, the near field link is continuously available and is used to "ping" the implantable medical device. The near field link is be used to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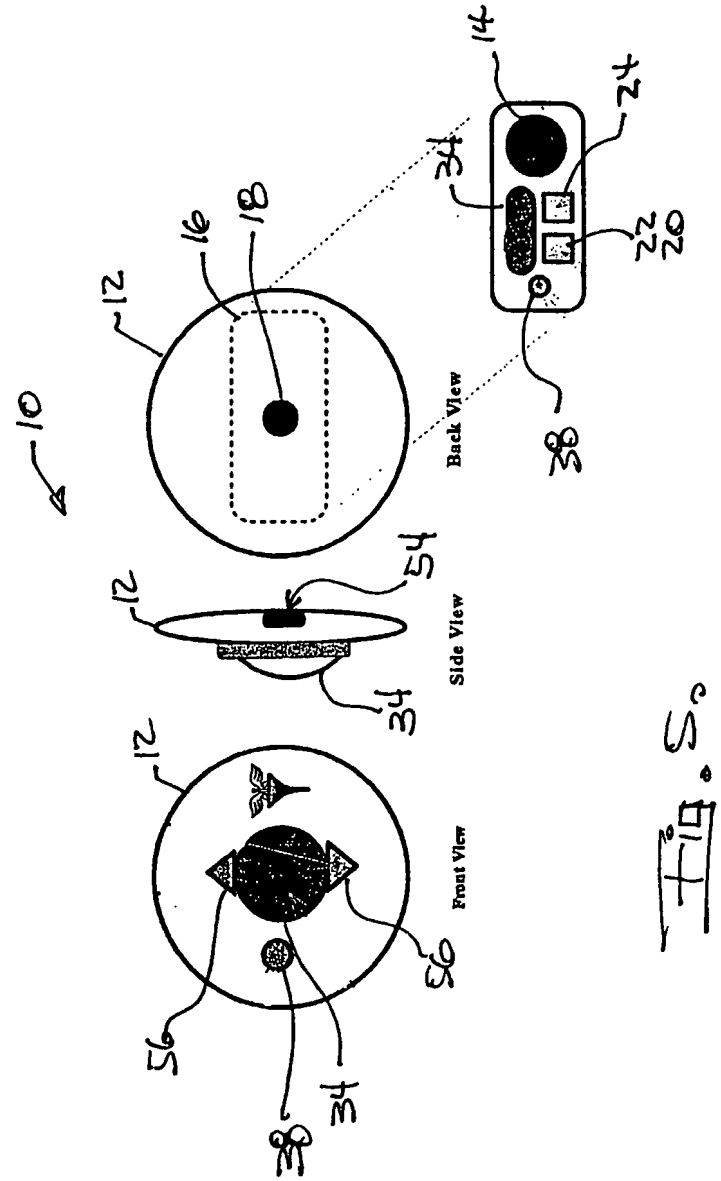
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Back View
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Side View
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Front View
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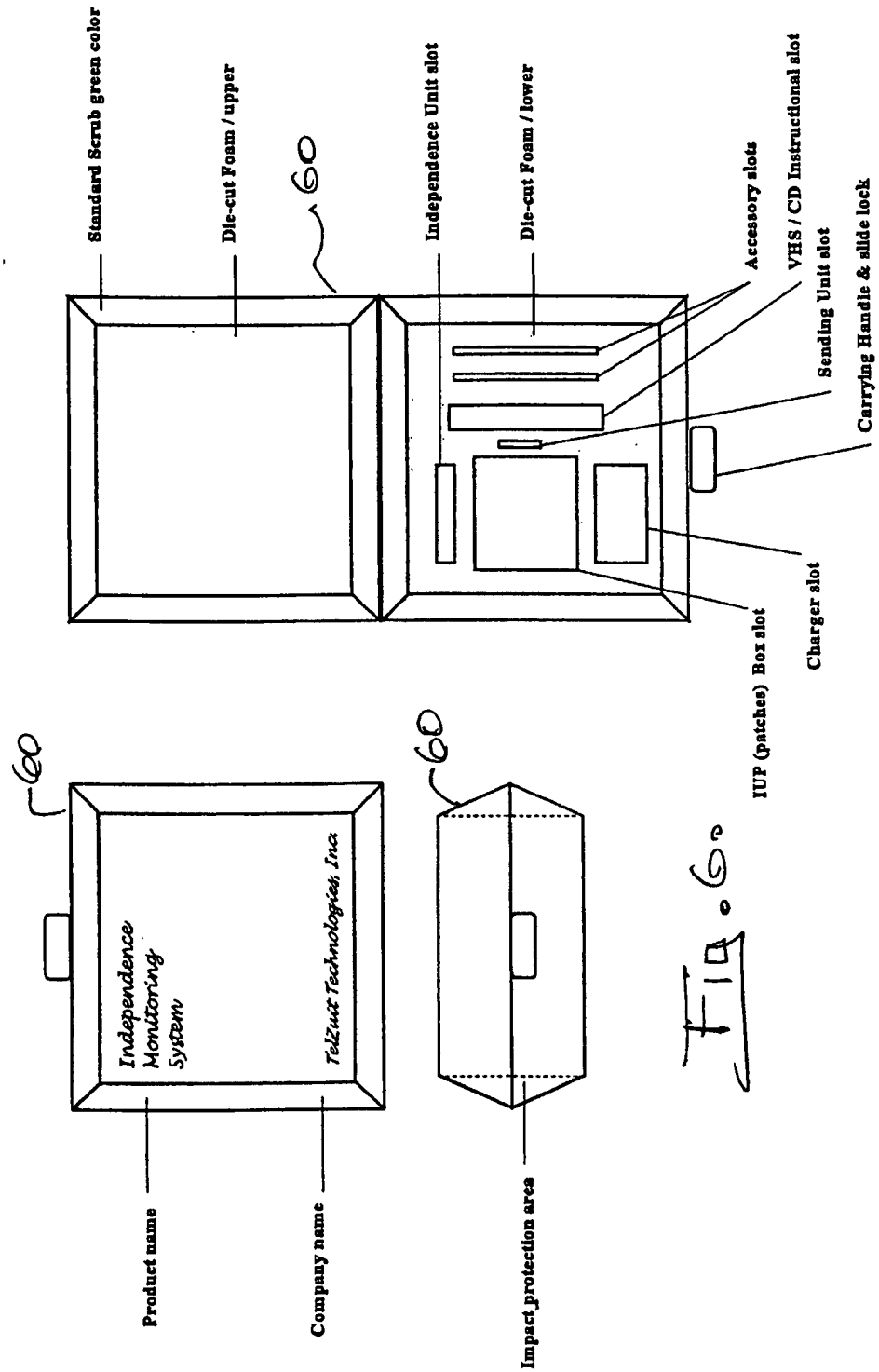
Fig. 5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Independence Unit slot
Die-cut Foam / lower
Accessory slots
VHS / CD Instructional slot
Sending Unit slot
Carrying Handle & slide lock
IUP (patches) Box slot
Charger slot
60
Independence Monitoring System
TeleTrust Technologies, Inc.
Product name
Company name
60
Impact protection area

Fig. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US02/13966

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61B 5/0408

US CL :600/391, 392, 393, 509; 128/903

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/391, 392, 393, 509; 128/903

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,042,481 A (SUZUKI et al) 27 AUGUST 1991, see Figures 10 and 16.	4-6
Y	US 5,862,803 A (BESSON et al) 26 JANUARY 1999, see entire document.	1-34
Y, P	US 6,285,899 B1 (GHAEM et al) 04 SEPTEMBER 2001, see entire document.	1-34
Y, E	US 6,385,473 B1 (HAINES et al) 07 MAY 2002, see entire document.	1-34

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 17 JUNE 2002	Date of mailing of the international search report 02 AUG 2002
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer Lee S. Cohen Diane Smith Telephone No. (703) 308-2998

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